Exhibit 4

Experiment Report:

Assessment of the Liver Toxicity of Oxy-Elite Pro in Mice

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Aim: The objective of this project was to investigate hepatotoxicity of Oxy-Elitte-Pro Products

Abstract:

Oxy-Elite Pro has been widely applied for building muscle and weigh lose. However, there are increasing concerns about its untoward effect. Recent cases report have shown concern about the potential association between OxyElite Pro and hepatotoxicity. This study examined the effects of OxyElite Pro products from market on male mice dosed intra-gastric for 7 days. Mortality, body and liver weight, and blood levels of alanine transaminase (ALT), alkaline phosphatase (ALP), blood urea nitrogen (BUN) were determined for assessment of liver injury. The results showed no mortality in mice administered daily doses of 0.78, 1.55, 6.25 mg/mouse for 7 days. However, it showed 100% mortality in mice administered daily higher doses of 12.5, 25 50 mg/mouse. Under regular dose of 6.25 mg/mouse for 7 days, body weight, relative liver weights did not show any alteration. Blood biochemical parameters ALT, ALP and BUN did not show any significant alteration indicating no effect on liver. Mice injected with an IP dose of 6mg/kg of LPS and dosed orally with the OxyElite Pro products at doses (0.78, 1.55, 6.25 mg/mouse also did not show any untoward effect on liver based on the blood chemical analysis

In summary, under regular dose (beneath 6.25 mg/mouse), Oxyellite Pro did not cause animal death and liver toxicity even under inflammatory stimulus. However, OxyElite Pro at higher dose of 12.5, 25, 50 mg/mouse caused 100% animal death.

Introduction

USPlabs' OxyElite Pro, one of the most popular weight loss supplements currently on the market. According to the manufacturer, OEP increases the user's metabolic function, enabling

people to burn calories even while they are at rest. Additionally, USPlabs claims that OxyElite Pro is designed to suppress appetite, increase energy, and even improve mood. Side effects of black cohosh are rarely reported. A recent cases report attracts FDA's attention. On the report, it is stated that 56 cases had been identified. Among these cases, 22 people have been hospitalized, two people have received liver transplants, and one person has died (). The FDA along with the Centers for Disease Control and Prevention (CDC) and state and local health officials are investigating acute hepatitis illnesses linked to products labeled OxyElite Pro. (Oct 10, 2013). Following actions by the Food and Drug Administration (FDA), a Texas-based company has agreed to recall and destroy a dietary supplement.

However, less evidences showed potential association between OxyEllite Pro and hepatotoxicity. No information on study design or details of the experiment was reported in the available literature. This study examined the effects of OxyEllite Pro products from market on female mice survival, body weight, liver, kidney and blood biochemical parameters after 7 days administered orally OxyEllite Pro.

Materials and Methods

***Materials*:** OxyEllite Pro Capsules were purchased from USP Labs. The contents of capsules were dissolved in 10% DMSO.

Animal model Female ND-4 mice at 4 weeks of age and 20 - 24 g body weight, housed in micro isolator cages with corn cob bedding, on 12 h light/dark cycle, at 72 °F and 35-50% relative humidity. Mice were fed on Purina 5001 laboratory chow and water *ad libitum*. Before administering any treatment, mice were fasted for 12 h. Food was made available *ad libitum* after treatment. Animals were divided into 7 groups: normal control group, vehicle control group and 5 groups of BC. Male mice were divided into 9 groups: normal control group, vehicle control group and 7 groups of Oxyelite Pro. Mice were fasted overnight and administered orally 0.78, 1.55, 3.12, 6.25, 12.5, 25 and 50 mg of OxyElite Pro per mouse, respectively. After drug treatment for 7 days, mice were anesthetized with isoflurane for sample collection. In acute inflammatory model, mice were given LPS 6 mg/kg once and 0.78, 1.55, 3.12, 6.25 mg of OxyElitePro daily for 7 days.

Note: All animal study protocols were approved by the IACUC, University of Mississippi.

Sample collection Mouse blood samples were obtained by intra-cardiac puncture. After blood withdrawal, mice were sacrificed by cervical dislocation. Liver and kidney samples were obtained, and preserved in 10% buffered formalin for histopathological analysis.

Biochemical analysis Plasma levels of alanine transaminase (ALT), alkaline phosphatase (ALP), blood urea nitrogen (BUN) were analyzed immediately using an automated VetScan VS2 blood chemistry analyzer (Abaxis, Union city, CA).

Histopathological evaluation: Livers were processed routinely and embedded in paraffin blocks. Liver sections were prepared (4 μm) and stained with hematoxylin (RICCA Chemical Co., Arlington, TX) and eosin (EMD Chemicals, Gibbstown, NJ). The slides were blindly observed and analyzed using a light microscope for liver injury.

Statistical analysis: Data was analyzed by one way ANOVA test followed by Tukey Cramer multiple comparisons using Graph Pad Prism software (La Jolla, CA). A P-value of less than 0.05 was considered to show a significant difference between the vehicle and other groups.

Results:

Experiment A: Effects of administration of Effects of OxyElite Pro on animal survival, plasma liver biomarkers and liver weight

1. ***Animal Survival***

   Administration of OxyElite Pro in daily doses of 0.78, 1.55, 3.12, and 6.25 /mouse IG for 7 days (group 5, 6) showed 0 mortality of animals. However, Administration of OxyElite Pro of 12.5, 25 and 50 /mouse IG showed 100% mortality of animals. All animals died in 6 hours after dosed (Table 1).

Table 1. Animal survival. Mice were fasted overnight administered orally 0.78, 1.55, 3.12, 6.25, 12. 5, 25, and 50 mg of OxyElite Pro respectively for 7 days.

Group No.	**Route**	**Mice No**	**Death of mice**	**Mortality (%)**
G1 (Vehicle 200 uL)	IG	3	0	0
G8 (OEP 0.78 mg/mouse once daily)	IG	3	0	0
G7 (OEP 1.55 mg/mouse once daily)	IG	3	0	0
G6 (OEP 3.12 mg/mouse once daily)	IG	3	0	0
G2 (OEP 6.25 mg/mouse once daily)	IG	3	0	0
G3 (OEP 12.5 mg/mouse once daily)	IG	3	3	100
G4 (OEP 25 mg/mouse once daily)	IG	3	3	100
G5(OEP 50 mg/mouse once daily)	IG	3	3	100

2. ***Body weight***

The body weight showed no alteration between vehicle control group and OxyElite Pro group**.**

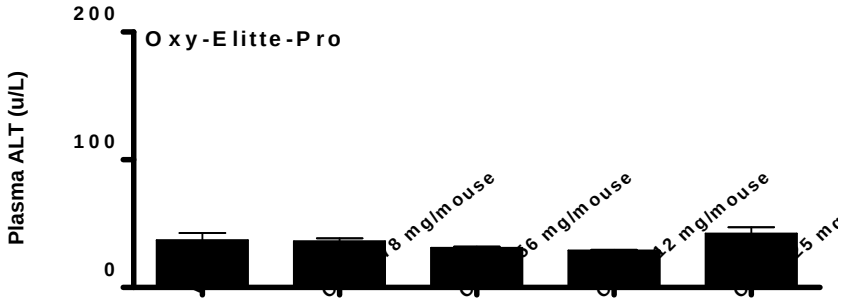
Table 2. Effects of OxyElite Pro on the body weight in ND-4 male mice.

Group No.	drugs	routes	Mice No.	Body weight (g) 0 day	3 days	7 days
G1	(Vehicle 200 uL)	IG	5	17.53 ± 5.34	18.40 ± 5.76	21.43 ± 3.56
G2	(OEP 0.78 mg/mouse once daily)	IG	3	21.35 ± 0.28	23.08 ± 0.51	24.41 ± 0.98
G3	(OEP 1.55 mg/mouse once daily)	IG	3	20.80 ± 0.56	20.97 ± 1.74	22.54± 1.32
G4	(OEP 3.12 mg/mouse once daily)	IG	3	22.03 ± 1.39	22.08 ± 1.56	25.19 ± 2.39
G5	(OEP 6.25 mg/mouse once daily)	IG	3	20.49 ± 0.37	21.92 ± 0.92	21.54 ± 0.41

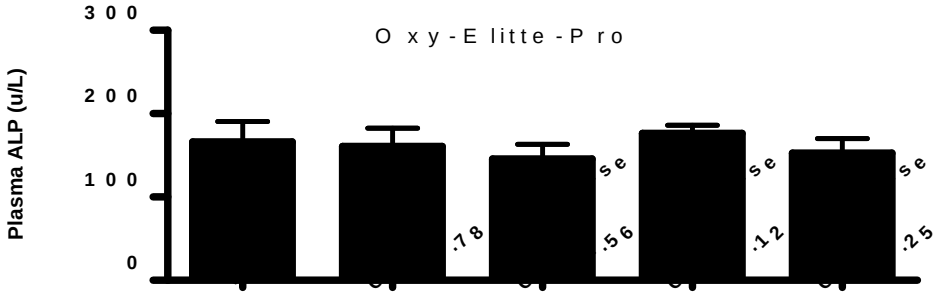
3. ***The toxicity of OxyElite Pro on liver***

a. ***Liver function:*** To determine the toxicity of OxyElite Pro, three main biochemical markers of hepatic toxicity, ALP, ALT and BUN were measured in serum of ND-4 male mice with or without 0.78, 1.55, 3.12, and 6.25 mg of OxyElite Pro treatment for 7 days (Figure 1A, B, C). There was no difference in serum ALP, ALT and BUN between untreated and treated ND 4 mice.

(A)


200
Oxy-Elitte-Pro
Plasma ALT (u/L)
100
0
8 mg/mouse
6 mg/mouse
2 mg/mouse

(B)


300
Oxy-Elitte-Pro
Plasma ALP (u/L)
200
100
0
.78
.56
.12
.25

(C)


200
Oxy-Elitte-Pro
Plasma BUN (mgD/L)
100
0
.78 mg/mouse
.56 mg/mouse
.12 mg/mouse

Fig. 1. Effects of OxyElite Pro on plasma ALT (A), ALP (B) and BUN (C) level in mice.

b. Relative liver weight

Administration of *OxyElite Pro* IG 0.78, 1.55, 3.12, and 6.25 mg for 10 days showed no effects on relative liver weights compared to control (Figure 2).

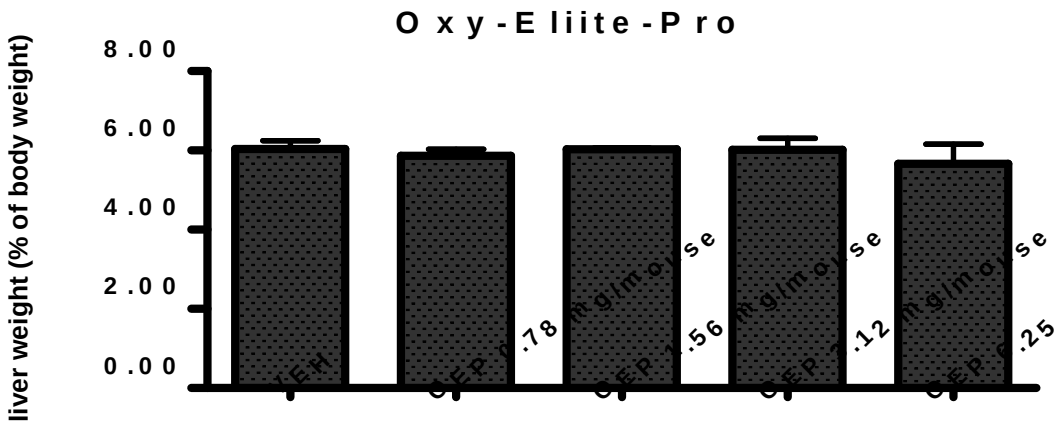


Figure 2. Relative liver weight of mice exposed toOxyElite Pro. Each value is a mean of mean ± SEM.

c. ***Histopathology examination***: Histopathologic evaluation of hepatic tissue sections stained with hematoxylyn and erosin revealed no evidence of acute hepatic injury.

Experiment B: Effect of OxyElite Pro with LPS (IP) on animal survival, serum liver biomarkers and liver weights and liver morphology

1. ***Animal Survival***

Administration of a single dose of LPS 6 mg/kg IP on the 1st day of continuous treatment with OxyEliete Pro at daily doses of 0.78, 1.55, 3.12, and 6.25 mg of OxyElite Pro IG for 7 days showed 0 mortality of animals (Table 3).

Table 3. Effects of OxyElitte Pro (OEP) +LPS on male mice survival.

Group	Route	Mice No	Death of mice	Mortality (%)
G9 (Vehicle 200 uL)	IG	3	0	0
G13 (OEP 0.78 mg/mouse once daily)	IG	3	0	0
G12 (OEP 1.55 mg/mouse once daily)	IG	3	0	0
G11 (OEP 3.12 mg/mouse once daily)	IG	3	0	0
G14 (OEP 6.25 mg/mouse once daily)	IG	3	0	0

2. ***Body weight***

Administration of *OxyElite Pro* at daily doses of 0.78, 1.55, 3.12 and 6.25 mg/mouse IG for 7 days showed no effects on relative liver weights compared to control (Table 4).

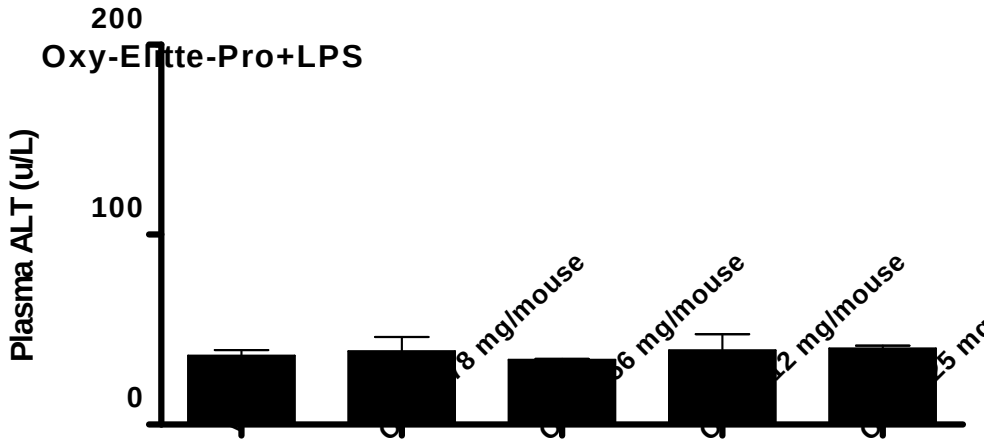
Table 4. Effects of OxyElite Pro with LPS on mice body weight.

Group No.	drugs	routes	Mice No.	Body weight (g) 0 day	3 days	7 days
9	(Vehicle 200 uL)	IG	3	21.46 ± 1.97	22.45 ± 1.39	22.64 ± 1.31
13	OEP 0.78 mg/mouse once daily)	IG	3	23.96 ± 1.76	24.90 ± 1.27	25.40 ± 1.70
12	(OEP 1.55 mg/mouse once daily)	IG	3	22.93 ± 0.69	24.78 ± 0.21	24.92 ± 0.61
11	(OEP 3.12 mg/mouse once daily)	IG	3	23.34 ± 0.42	25.41 ± 0.82	24.12 ± 0.80
14	(OEP 6.25 mg/mouse once daily)	IG	3	24.17 ±0.46	26.37 ± 0.55	25.32 ± 0.13

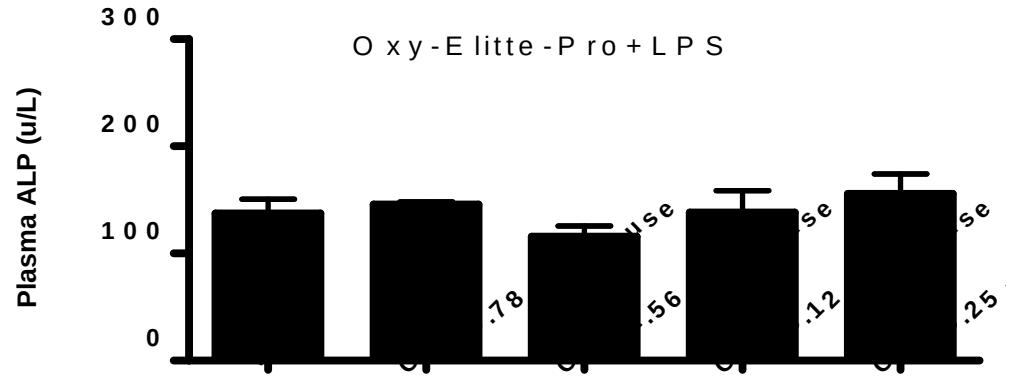
3. The toxicity of BC on liver

a. Liver function: Administration of a single dose of LPS 6 mg/kg IP on the 1th day of continuous treatment with C. racemosa, C. foetida at daily doses of 0.78, 1.55, 3.12, and 6.25 mg/mouse IG for 7 days, three main chemical parameters (ALT, ALP and BUN) did not show significant changes compare to control

(A)



(B)



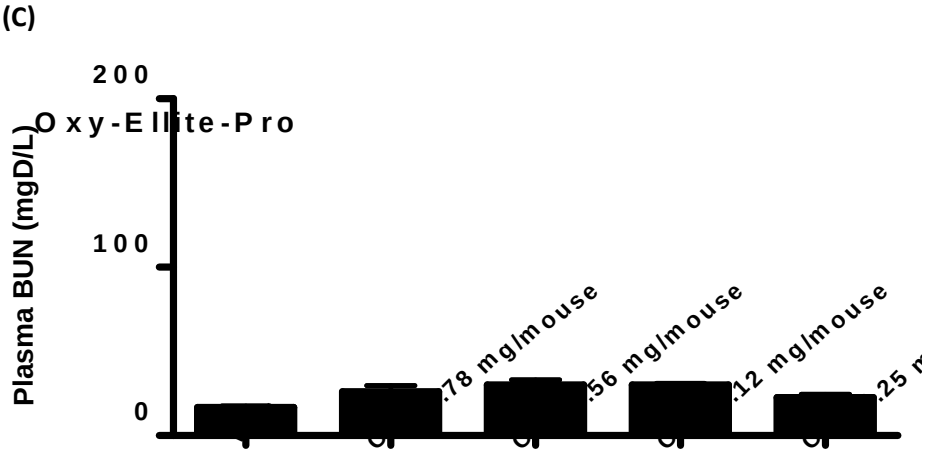


Fig. 3. Effects of OxyElite Pro on plasma ALT, ALP, and BUN level in mice.

b. Relative liver weight

Administration of a single dose of LPS 6 mg/kg IP on the 1th day of continuous treatment with OxyElite Pro at daily doses of 0.78, 1.55, 3.12, and 6.25 mg/mouse for 7 days showed no effects on relative liver weights (Fig. 4).

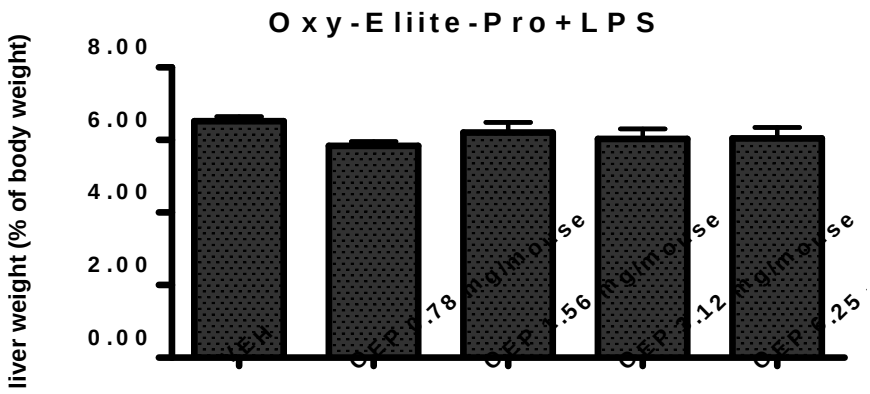


Fig 4. Relative liver weight of mice exposed to OxyElite Pro with LPS. Each value is a mean of mean ± SEM; Statistical difference from the control:

c. Histopathology examination:

Discussion

OxyElite Pro is a dietary supplement. Each capsule of OxyElite Pro contains 119.5 mg proprietary blend (Bauhinia Purpurea L. (Leaf And Pod) Extract, Bacopa (Leaf) (Bacopa Monnieri) Extract, 1,3-Dimethylamylamine HCL, Cirsium Oligophyllum (Plant) Extract, Yohimbe (Pausinystalia Johimbe) Bark Extract) and 100 mg caffeine. Adult take two capsules per day. This dose is transferred into animal dose. It is equal to 6.24 mg/mouse per day. This study revealed no mortality in mice administered daily doses of 0.78, 1.55, 6.25 mg/mouse for 7 days. However, OxyElite Pro showed 100% mortality in mice administered daily higher doses of 12.5, 25 50 mg/mouse. Under regular dose of 6.25 mg/mouse for 7 days, body weight, relative liver weights did not show any alteration. Blood biochemical parameters ALT, ALP and BUN did not show any significant alteration indicating no effect on liver. Mice injected with an IP dose of 6mg/kg of LPS and dosed orally with the OxyElite Pro products at doses (0.78, 1.55, 6.25 mg/mouse also did not show any untoward effect on liver based on the blood chemical analysis

In summary, under regular dose (beneath 6.25 mg/mouse), Oxyellite Pro did not cause animal death and liver toxicity even under inflammatory stimulus. However, OxyElite Pro at higher dose of 12.5, 25, 50 mg/mouse caused 100% animal death.

ACKNOWLEDGMENT

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References